

The rejection of Claims 1-15 is based on the unsupportable assumption that it would have been obvious to combine the Fain adapter and the Stutz lead into a unitary lead and adapter. The obviousness rejection relies on the assertion that the use of a one piece construction instead of a two piece lead and adapter construction is an "obvious engineering choice." Applicants respectfully point out that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive to support the combination. Stutz and Fain fail to teach, suggest or provide incentive for combining the two references to make the claimed inventions in the subject application. Therefore, the rejection of rejected Claims 1-15 under 35 U.S.C. § 103(a) as obvious is improper.

In support of the rejection of claims 1-15 as an "obvious engineering design choice" the office action relies on In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). The rejection in In re Larson was based on a single prior art reference comprising several parts rigidly secured together as a single unit. The decision in In re Larson of obvious design choice was not based on a combination of references, but rather was considering the teachings of a single reference.

All claim limitations of a claim must be considered, especially when a claimed limitation is missing from the relied on prior art reference. Nowhere does Stutz or Fain teach, suggest or provide motivation for a lead having an adapting member formed as part of the lead. The claimed adapter integrated into a lead body eliminates components. Further, although the office action asserts that a one piece lead and adapter construction instead of a two piece construction would have been a matter of "obvious engineering choice," the office actions fail to cite a single reference showing such a one piece lead and adapter construction. The absence of such a

showing further supports applicant's position that such a combination is not an obvious engineering choice.

The office action also asserts that it has no bearing on the issue of obviousness, whether the cited references serve a different purpose and perform a different function than the claimed device. Applicant respectfully points out that Fain's purpose and function is to convert a lead connector port configuration on the header assembly of an implantable cardiac stimulation device to a different port configuration through the use of an adapter. Fain's purpose and function is different from the subject application. Once the can of the pacer has been implanted it may be desirable to exchange leads without removing the can. Also it may be desirable to provide multiple leads plugged into a single port of an implanted can. The Fain adapter does not serve this purpose. A further indication of the differences between the claimed adapter lead arrangement and the teachings of the prior art. One purpose and function of the claimed invention is to reduce the number of sealing ports to reduce corrosion and the need to repair or replace the device. Also, the claimed invention reduces the total number of required component parts. The differing purpose and function of the claimed device further evidences the non-obviousness of the claimed invention from the prior art references. Thus, the purpose and function of the subject application is different from Fain, and the rejection of rejected Claims 1-15 under 35 U.S.C. § 103(a) as obvious is improper.

Further, none of the references relied on in the office actions show or describe a jumper wire connecting a terminal block of an adapting member and a conductor of a lead. The office action fails to identify any references that show a jumper wire connecting a terminal block of an adapter to the conductor of a lead. This claimed limitation alone distinguishes the claimed

invention from the teachings of the prior art. Therefore, the rejection of rejected Claims 1-15 under 35 U.S.C. § 103(a) as obvious is improper.

Additionally, the office action indicates that “any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning,” and that “so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.” The office action has failed, however, to provide any evidence to support the assertion of obviousness to one skilled in the art. It is impermissible to engage in hindsight reconstruction of the claimed invention using the applicant's structure as a template and selecting elements from references to fill in the gaps. Hence, the rejection of rejected Claims 1-15 under 35 U.S.C. § 103(a) is improper.

The office action further indicated that claim 2 is rejected with regard to Fain in combination with a lead. The office action provides that such a combination results in an adapting member that is positioned on the lead adjacent to the proximal end of the main body of the lead. Applicant respectfully traverses the rejection as applied to Claim 2. First, since Claim 1 is not obvious over Fain in view of Stutz for the reasons stated above regarding the rejection of Claims 1-15 under 35 U.S.C. § 103(a), all claims dependent from Claim 1 are also non-obvious in view of Fain in combination with a lead. Second, obviousness cannot be established by combining the teachings of the prior art, absent some teaching, suggestion or incentive to support the combination. Fain fails to teach, suggest or provide incentive for combining a lead with the adapter as claimed. The claimed invention reduces the number required ports and reduces the potential occurrence of corrosion by eliminating ports. The claimed adapter and lead

combination simplifies the ability to simultaneously stimulate a plurality of leads attached to a single port of the header. Thus, the rejection of claim 2 is improper.

The office action also rejects Claims 4, 5, 11 and 12 as obvious, and provides that the Fain device could be modified such that the lead connector port and the lead connector could be replaced by an aperture through the adapter so that the adapter would not interfere with another lead connected directly to a port on the header, and that the inclusion of such an aperture would have been a modification of the shape of the adapter which to a person of ordinary skill in the art would have been obvious. The office action further asserts that the shape of the Fain adapter could have been modified in any number of obvious ways so that the shape of the adapter would not interfere with other leads being connected directly to the header. Applicant respectfully traverses the above rejection as applied to Claims 4, 5, 11 and 12. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification. Fain does not teach or suggest the desirability of the aperture, or the modification of the shape of the adapter. Therefore, the rejection of the rejected Claims 4, 5, 11 and 12 as obvious is improper.

When a claimed element is absent from the teachings of a reference, there must be a suggestion to combine the teachings of other relied upon references. The mere fact that references might be able to be combined or modified in a manner suggested, does not render the resultant combination obvious unless the references also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ.2d 1430 (Fed. Cir. 1990). It appears that hindsight has been used to reconstruct the claimed invention from the cited references. "It is impermissible however, simply to engage in a hindsight reconstruction of the claimed invention,

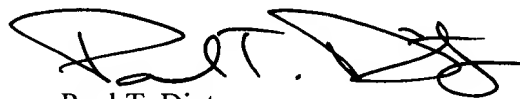
using the applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 18 USPQ.2d 1885 (Fed. Cir. 1991). Each of the claims include limitations that are not shown or described by the cited references. Further, a prima facie case of obviousness can only be established by combining or modifying the teachings of the cited references to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ.2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ.2d 1941 (Fed. Cir. 1992); (see MPEP 2143.01).

Thus, the rejection to independent claims 1 and 9 should be withdrawn and the claims should be allowed. Likewise, the rejection of dependent claims 2-8 and 10-15 should be withdrawn and allowed. The office action fails to establish a prima facie case of obviousness and as such claims 1-15 are believed to be in a condition of allowance and a notice to that affect is respectfully requested. The amendments and remarks set forth above are provided to expedite and advance the prosecution of the patent application.

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Respectfully submitted,

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